subsection, the Secretary may require that a sponsor who, for reasons not satisfactory to the Secretary, fails to complete by its deadline a study under any of such sections of such type for a drug or biological product (including such a study conducted after such effective date) notify practitioners who prescribe such drug or biological product of the failure to complete such study and the questions of clinical benefit, and, where appropriate, questions of safety, that remain unanswered as a result of the failure to complete such study. Nothing in this subsection shall be construed as altering the requirements of the types of studies required under section 356(b)(2)(A) of this title or under section 314.510 or 601.41 of title 21, Code of Federal Regulations, as so in effect, or as prohibiting the Secretary from modifying such sections of title 21 of such Code to provide for studies in addition to those of such type.

(June 25, 1938, ch. 675, § 506B, as added Pub. L. 105–115, title I, § 130(a), Nov. 21, 1997, 111 Stat. 2331; amended Pub. L. 107–188, title V, § 506, June 12, 2002, 116 Stat. 693.)

REFERENCES IN TEXT

The effective date of this subsection, referred to in subsec. (e), is Oct. 1, 2002, see Effective Date of 2002 Amendment note set out below.

AMENDMENTS

2002—Subsecs. (d), (e). Pub. L. 107–188 added subsecs. (d) and (e).

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107–188, title V, § 508, June 12, 2002, 116 Stat. 694, provided that: ''The amendments made by this subtitle [subtitle A (§§ 501–509) of title V of Pub. L. 107–188, amending this section and sections 379g and 379h of this title] shall take effect October 1, 2002.''

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

REPORT TO CONGRESSIONAL COMMITTEES

Pub. L. 105–115, title I, § 130(b), Nov. 21, 1997, 111 Stat. 2331, provided that not later than Oct. 1, 2001, the Secretary was to submit to Congress a report containing a summary of the reports submitted under section 356b of this title and an evaluation and legislative recommendations relating to postmarketing studies of drugs.

§ 356c. Discontinuance of life saving product

(a) In general

A manufacturer that is the sole manufacturer of a drug—

(1) that is—

(A) life-supporting;

(B) life-sustaining; or

(C) intended for use in the prevention of a debilitating disease or condition;

(2) for which an application has been approved under section 355(b) or 355(j) of this title; and

(3) that is not a product that was originally derived from human tissue and was replaced by a recombinant product,

shall notify the Secretary of a discontinuance of the manufacture of the drug at least 6 months prior to the date of the discontinuance.

(b) Reduction in notification period

The notification period required under subsection (a) of this section for a manufacturer may be reduced if the manufacturer certifies to the Secretary that good cause exists for the reduction, such as a situation in which—

(1) a public health problem may result from continuation of the manufacturing for the 6-month period;

(2) a biomaterials shortage prevents the continuation of the manufacturing for the 6-month period;

(3) a liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period;

(4) continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer;

(5) the manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11; or

(6) the manufacturer can continue the distribution of the drug involved for 6 months.

(c) Distribution

To the maximum extent practicable, the Secretary shall distribute information on the discontinuation of the drugs described in subsection (a) of this section to appropriate physician and patient organizations.

(June 25, 1938, ch. 675, § 506C, as added Pub. L. 105–115, title I, § 131(a), Nov. 21, 1997, 111 Stat. 2332.)

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

§ 357. Repealed. Pub. L. 105–115, title I, § 125(b)(1), Nov. 21, 1997, 111 Stat. 2325

Section, act June 25, 1938, ch. 675, § 507, as added July 6, 1945, ch. 281, § 3, 59 Stat. 463; amended Mar. 10, 1947, ch. 16, § 3, 61 Stat. 12; July 13, 1949, ch. 305, § 2, 63 Stat. 409; Aug. 5, 1953, ch. 334, § 2, 67 Stat. 389; Pub. L. 87–781, title I, §§ 105(a), (b), (d)–(f), 106(a), (b), Oct. 10, 1962, 76 Stat. 785, 786, 787; Pub. L. 90–399, § 105(b), July 13, 1968, 82 Stat. 352; Pub. L. 102–300, § 6(b)(2), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, § 3(p), Aug. 13, 1993, 107 Stat. 777, related to certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug.

§ 358. Authority to designate official names

(a) Necessity or desirability; use in official compendiums; infringement of trademarks

The Secretary may designate an official name for any drug or device if he determines that such action is necessary or desirable in the interest of usefulness and simplicity. Any official name designated under this section for any drug or device shall be the only official name of that drug or device used in any official compendium published after such name has been prescribed or for any other purpose of this chapter. In no event, however, shall the Secretary establish an official name so as to infringe a valid trademark.

(b) Review of names in official compendiums

Within a reasonable time after October 10, 1962, and at such other times as he may deem